

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NEW YORK

SMITHKLINE BEECHAM CORPORATION,  
and BEECHAM GROUP, p.l.c.,

Plaintiffs,

v.

EON LABS MANUFACTURING, INC.,

Defendant.

CV 98 1611

CIVIL ACTION NO.

COMPLAINT FOR PATENT INFRINGEMENT

For their complaint herein, Plaintiffs allege as  
follows:

THE PARTIES

1. Plaintiff, SmithKline Beecham Corporation ("SmithKline Beecham"), is a corporation incorporated under the laws of the Commonwealth of Pennsylvania having its principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania 19101.

2. Plaintiff, Beecham Group p.l.c. ("Beecham Group"), is a United Kingdom corporation having its principal place of business at Brentfort, United Kingdom.

3. Upon information and belief, Defendant, Eon Labs Manufacturing, Inc. ("Eon"), is a corporation incorporated under the laws of the State of Delaware, having its principal place of business at 227-15 N. Conduit Avenue, (Laurelton) Springfield Gardens, New York 11413 in the Eastern District of New York.

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SIFTON

POLLAK

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JURISDICTION AND VENUE

4. This action arises under the patent laws of the United States of America and jurisdiction is founded on Title 28, United States Code §§ 1331 and 1338(a). On information and belief, jurisdiction is proper in this Court because Eon is licensed to do business in the State of New York, and has its principal place of business and does business within this judicial district. Venue is proper in this Court under Title 28, United States Code §§ 1391(c) and 1400(b).

5. SmithKline Beecham is the owner of approved New Drug Application 19-583 by which the United States Food & Drug Administration ("USFDA"), on December 24, 1991, first granted approval for the compound commonly known as "nabumetone". Nabumetone has been shown to have anti-inflammatory activities in humans and is prescribed for pain relief particularly to arthritis patients. SmithKline Beecham sells nabumetone under license from Beecham Group under the trademark Relafen®.

6. Beecham Group is the owner of United States Patent No. 4,420,639 ("the '639 Patent"), which discloses and claims nabumetone, a compound claimed by its chemical name 4-(6'-methoxy-2'naphthyl)butan-2-one. The '639 Patent was duly and legally issued on December 13, 1983. On May 20, 1993, the United States Patent and Trademark Office extended the term of the '639 Patent for a period of two years. Hence, the '639 Patent will expire on December 13, 2002. A

copy of the '639 Patent and Certificate Extending The Patent Term is attached as Exhibit A.

CLAIM

7. Eon has filed in the USFDA an Abbreviated New Drug Application ("ANDA"), No. 75-280, and has, in connection with that ANDA, filed a certification with respect to the '639 Patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355) seeking approval to sell nabumetone. Plaintiff SmithKline Beecham received notice of the certification on January 26, 1998. A copy of Eon's Patent Certification Notice to SmithKline Beecham is attached as Exhibit B.

8. Because Eon seeks approval of its ANDA to engage in the commercial manufacture, use or sale of nabumetone as claimed in the '639 Patent before the patent's expiration, Eon has infringed the '639 Patent pursuant to 35 U.S.C. § 271(e)(2)(A).

9. SmithKline Beecham and Beecham Group are entitled to the relief provided by 35 U.S.C. § 271 (e)(4), including an order of this Court that the effective date of the approval of Eon's ANDA be a date which is not earlier than the December 13, 2002 expiration of the '639 Patent.

10. On information and belief, Eon was aware of the existence of the '639 Patent and was aware that the filing of its ANDA and certification with respect to the '639 Patent constituted an act of infringement of that patent.

11. Eon acted without a reasonable basis for a good faith belief that it had a right to infringe the '639 Patent.

12. Eon's infringement of the '639 Patent was and is willful.

13. This case is an exceptional one, and SmithKline Beecham and Beecham Group are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

14. As and to the extent Eon has committed any act with respect to the compound claimed in the '639 Patent other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), SmithKline Beecham and Beecham Group are entitled to an award of damages for such actions, which this Court should increase threefold pursuant to 35 U.S.C. § 284.

PRAYER FOR RELIEF

Plaintiffs request that:

a. Judgment be entered that Defendant Eon has infringed the '639 Patent by submitting the aforesaid ANDA;

b. A permanent injunction be issued pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining said Defendant, its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of nabumetone as covered by the '639 Patent;

c. An order be issued pursuant to 35 U.S.C. § 271 (e) (4) (A) that the effective date of any approval of the ANDA be a date which is not earlier than the December 13, 2002 expiration date of the '639 Patent;

d. Judgment be entered for costs and reasonable attorney fees to be awarded to the Plaintiffs; and

e. For such other and further relief as the Court may deem proper under the circumstances.

Dated: New York, New York  
March 5, 1998

FITZPATRICK, CELLA, HARPER & SCINTO

By: 

Robert L. Baechtold (RB-6866)  
Henry J. Renk (HR-2995)  
Stevan J. Bosses (SB-4265)  
277 Park Avenue  
New York, New York 10172  
(212) 758-2400

Attorneys for Plaintiffs  
SmithKline Beecham Corporation  
and Beecham Group p.l.c.

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